

**REMARKS**

Claims 1-12 were pending in this application. Claims 1-12 were variously rejected under 35 U.S.C. § 103. Claims 1-12 have been objected to.

By this amendment, claim 2 has been canceled, claims 1, 3-9 and 11-12 have been amended, and claims 13 and 14 have been added without prejudice or disclaimer of any previously claimed subject matter. Support for the amendments can be found, *inter alia*, throughout the specification. Support for the amendment to claims 1 and 3 is found, *inter alia*, at page 4, lines 4-6, and support for new claims 13 and 14 is found, *inter alia*, in originally filed claims 4 and 7, respectively.

The amendments are made solely to promote prosecution without prejudice or disclaimer of any previously claimed subject matter. With respect to all amendments and canceled claims, Applicants have not dedicated or abandoned any unclaimed subject matter and moreover have not acquiesced to any rejections and/or objections made by the Patent Office. Applicants expressly reserve the right to pursue prosecution of any presently excluded subject matter or claim embodiments in one or more future continuation and/or divisional application(s).

Applicants have carefully considered the points raised in the Office Action and believe that the Examiner's concerns have been addressed as described herein, thereby placing this case into condition for allowance.

**Claim Objections**

Claims 1-12 were objected to because of an allegedly improper amendment submitted with the application. The amendment was not entered. Applicants have herein provided claim amendments in a proper form. For clarity, the amendments herein are presented based on the originally filed claims (as found in the corresponding publication US 2002-0055135 A1).

Applicants respectfully request entry of this amendment and withdrawal of the claim objections.

Rejections under 35 U.S.C. §103

Claims 1-9, 11 and 12 were rejected under 35 U.S.C. §103 as allegedly being unpatentable over Jaeger (U.S. Pat. No. 3,268,606) in view of Sarnecki (U.S. Pat. No. 3,356,753). Claims 1-12 were rejected under 35 U.S.C. §103 as allegedly being unpatentable over Jaeger in view of Sarnecki, and further in view of Rose et al. (U.S. Pat. No. 5,378,369, "Rose") and Bohinski et al. (U.S. Pat. No. 3,492,202, "Bohinski"). Applicants respectfully traverse these rejections.

A *prima facie* case of obviousness requires that three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20USPQ2d 1438 (Fed. Cir. 1991); MPEP §2143. If any one of these three criteria is not met, a *prima facie* case of obviousness has not been established. As presented below, Applicants respectfully submit that a *prima facie* case of obviousness has not been established.

The claimed invention is directed to a process for isolation of a crystalline carotenoid compound from a microbial biomass. The claimed process comprises disrupting the microbial cell walls, separating cellular debris from residue containing the carotenoid crystals, washing the carotenoid crystal containing residue with a solvent to remove lipid, suspending the carotenoid crystals in water to float the crystals and remove biomass debris and recovering the carotenoid crystals.

The claimed process involves the direct separation of the carotenoid crystals from the microbial biomass without solubilizing the carotenoid crystals. Both Jaeger and Sarnecki, however, describe processes in which carotenoids are solubilized and then crystallized.

Jaeger describes a process of isolating  $\beta$ -carotene crystals that involves solubilization of  $\beta$ -carotene with a solvent followed by crystallization of the  $\beta$ -carotene. See, for example, column 1, lines 15-20. Sarnecki describes a process for production of pure carotenoids which uses water and a water-soluble surfactant. Sarnecki states that "a particularly important embodiment of the process according to this invention is to dissolve the carotenoid in the solubilizer and to introduce the solution into water with vigorous stirring or to add water with vigorous stirring." Sarnecki, column 3, lines 5-12, emphasis added.

Thus, contrary to the instant claimed invention, the carotenoid isolation processes taught by Jaeger and Sarnecki rely on the solubilization and subsequent crystallization of carotenoid crystals. Accordingly, the cited references, alone or in combination, do not teach the claimed invention.

Further, there is no suggestion or motivation in the references or in the art to modify Jaeger and Sarnecki to arrive at the claimed invention. Applicants also submit that, as there is no teaching of the claimed invention, Jaeger and Sarnecki do not provide a reasonable expectation of success of the claimed invention.

Accordingly, the combination of Jaeger and Sarnecki do not support a *prima facie* case of obviousness. Thus, Applicants respectfully submit that the claimed invention is not obvious in view of Jaeger and Sarnecki.

Rose also describes a process of solvent extraction of  $\beta$ -carotene from a biomass suspension. For example, Rose teaches a process "whereby the  $\beta$ -carotene is caused to dissolve in

the organic phase, followed by separation of the organic phase from the aqueous phase.” Rose, column 1, lines 17-20, and column 4, lines 47-49.

The Examiner asserts that Bohinski “provides motivation for adding vegetable oil to the microbial cells before cell disruption.” Office Action, page 5. However, Bohinski describes a method for improving yields of  $\beta$ -carotene produced from aerobic cultivation of *Blakeslea trispora* in a nutrient media containing soapstock and does not describe a process for isolation of  $\beta$ -carotene crystals. Bohinski describes the amount of  $\beta$ -carotene produced by the cells when grown with oil or soapstock (see, for example, column 5, lines 5-8) but does not teach or suggest a method for isolating a crystalline carotenoid compound as claimed in the instant invention.

Neither Rose nor Bohinski supply what is missing from Jaeger in view of Sarnecki and the combinations of Jaeger, Sarnecki and the tertiary references do not teach or suggest the claimed invention, thus do not render the claimed invention obvious. None of the references, either alone or in combination, describes or suggests a process for isolation of carotenoid crystals without first solubilizing the  $\beta$ -carotene.

Further, Applicants submit that there is no suggestion in the art or in these references to modify their teachings to arrive at the claimed invention.

In sum, Applicants respectfully submit that a *prima facie* case of obviousness has not been made.

Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. §103.

### CONCLUSION

Applicants believe that all issues raised in the Office Action have been properly addressed in this response. Accordingly, reconsideration and allowance of the pending claims is respectfully requested. If the Examiner feels that a telephone interview would serve to facilitate

resolution of any outstanding issues, the Examiner is encouraged to contact Applicants' representative at the telephone number below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 246152019901. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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